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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT PAPER NUMBER

3736

DATE MAILED: 10/06/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/002,540

Applicant(s)

QUAY, STEVEN

Examiner

Charles A. Marmor, II

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15 and 45-49 is/are rejected.
- 7) ☒ Claim(s) 14, 16-44 and 50-54 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Amendment/Response filed June 24, 2003. The Examiner acknowledges the amendments to the Specification and to claims 3, 4, 6, 7, 10-16, 18, 19, 23-25, 28, 30, 32, 34, 35, 37, 38, 40, 42, 43, 45, 47, 48, 50, 51, 52 and 54. Claims 1-54 are pending.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because it does not provide support for the new claim for the benefit under 35 U.S.C. 120 of U.S. Application Nos. 10/404,866; 09/435,131; and 08/709, 207.

Priority

3. Applicant's claim for priority under 35 U.S.C. 120 is acknowledged. However, the priority claim was not filed within the time period provided by 37 CFR 1.78(a)(2)(ii) and Applicant has not filed a petition meeting the requirements for benefit claims filed outside of that time period as required by 37 CFR 1.78(a)(3). Moreover, Applicant's claim for benefits under 35 U.S.C. 120 is based on a later-filed application (i.e. U.S. Application No 10/404,866) which is

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improper under 35 U.S.C. 120. In view of the foregoing, Applicant's claim for the benefit under 35 U.S.C. 120 of U.S. Application Nos. 10/404,866; 09/435,131; and 08/709, 207 is not granted.

Claim Objections

4. Claim 22 is objected to because of the following informalities: in line 3, --member-- apparently should be inserted following "reservoir". Appropriate correction is required.

5. Claim 30 is objected to because of the following informalities: in line 2, --member-- apparently should be inserted following "reservoir" (second occurrence). Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 15, 47 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 recites the limitation "or vial" in line 3. There is insufficient antecedent basis for this limitation in the claim. As a result of the amendment filed June 24, 2003, there is no vial recited in the claims prior to this recitation.

Claim 47 recites the limitation "the sample collection housing" in line 3. There is insufficient antecedent basis for this limitation in the claim. There is no sample collection

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housing recited in claims 1 or 47 prior to this recitation. This rejection was made in the Office Action mailed March 18, 2003, but was not resolved by the amendment filed June 24, 2003.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(f) he did not himself invent the subject matter sought to be patented.

9. Claims 1-13, 45 and 46 remain rejected under 35 U.S.C. 102(e) as being anticipated by Quay et al. (521). Quay et al. teach a sample collection device including a breast engaging member constructed of a non-porous material sized and dimensioned to receive at least a nipple portion of a breast of said patient and form a suction seal therewith; a solid phase sample collection medium in fluid connection with said breast engaging member for receiving a sample of expressed breast fluid; and vacuum pump means in gaseous connection with said breast engaging member for generating negative pressure through the breast engaging member to facilitate breast fluid expression. The sample collection device is a hand-held breast pump incorporating said breast engaging member and vacuum pump means in a compact, structurally integrated breast fluid collection apparatus that can be manipulated and operated with one hand. The solid phase sample collection medium is selected from the group consisting of microscopic glass slides, capillary tubes, collection tubes, columns, micro-columns, wells, plates, membranes,

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filters, resins, inorganic matrices, beads, resins, particulate chromatographic media, plastic microparticles, latex particles, coated tubes, coated templates, coated beads, coated matrices, or a combination thereof. The hand-held breast pump is a modular device formed of a plurality of components that are joined or securable in fixed structural interconnection with one another and may be partially or completely disassembled. The solid phase sample collection medium is supported by a support member removably mounted in fluid connection with said breast engaging member. The support member is provided as a removable cassette that can be inserted within said breast engaging member to be removably mounted in fluid connection therewith. The support member supports one or more pads or sheets of absorbent or adsorbent material. The solid phase sample collection medium may be a nitrocellulose membrane having a pore size selected to effectively retain whole cells from expressed breast fluid on a surface of the membrane. The pad or sheet is a modified membrane or filter having perforations or slits that disrupt the planar surface of the membrane or filter to facilitate air passage therethrough. The support member incorporates one or more air channels that pass through a body of the support member. A fluid-retaining recess, well or reservoir is connected with the support member or a sample collection housing member of the hand-held pump device. The solid phase sample collection medium is adjustably mounted relative to the sample collection housing so that the solid phase collection medium can be controllably moved closer to, or farther away from, a base of the engaging member of the pump during use. A reciprocating mechanism adjustably moves the solid phase sample collection medium in closer, or more distant, proximity to the nipple.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 USC 102(e).

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This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

10. Claims 1-13, 45 and 46 remain rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. Quay et al. ('521), as discussed hereinabove, teach all of the limitations of the claims. The Quay et al. reference has a common inventor with the instant application, but the instant application eliminates a second inventor while claiming the same subject matter.

11. Claims 1-4, 12, 13 and 47-49 remain rejected under 35 U.S.C. 102(e) as being anticipated by Covington et al. ('513). Covington et al. teach an intraductal breast fluid aspiration device **20**. The device includes a breast engaging member **24** constructed of a non-porous material sized and dimensioned to receive at least a nipple portion of a breast of said patient and form a suction seal therewith; a solid phase sample collection medium (col. 4, lines 16-22) in fluid connection with said breast engaging member for receiving a sample of expressed breast fluid; and vacuum pump means **22** in gaseous connection with said breast engaging member for generating negative pressure through the breast engaging member to facilitate breast fluid expression. The sample collection device is a hand-held breast pump incorporating said breast engaging member and vacuum pump means in a compact, structurally integrated breast fluid collection apparatus that can be manipulated and operated with one hand. The solid phase sample collection medium is a

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membrane (col. 4, lines 16-22). The hand-held breast pump is a modular device formed of a plurality of components that are joined or securable in fixed structural interconnection with one another and may be partially or completely disassembled (col. 12, lines 44-46). A fluid-retaining reservoir is connected with the support member or a sample collection housing member of the hand-held pump device (col. 4, lines 14-16). A compact vacuum pump housing integrates the vacuum pump with the sample collection housing and a vacuum pump actuating mechanism 25 is connected to a vacuum pump housing of the device.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1-8, 11, 12, 45 and 46 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-9 and 11 of U.S. Patent No. 6,287,521. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are merely broader than those of the patent. The claims of the patent recite all of the limitations of the claims of the

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instant application, and further recite additional limitations that are not recited in the instant application. The limitations of claims 1, 2 and 8 of the instant application are recited in claim 1 of the patent. The limitations of claims 3 and 4 of the instant application are recited in claim 2 of the patent. The limitations of claim 5 of the instant application are recited in claim 3 of the patent. The limitations of claim 6 of the instant application are recited in claim 9 of the patent. The limitations of claim 7 of the instant application are recited in claim 5 of the patent. The limitations of claim 11 of the instant application are recited in claim 8 of the patent. The limitations of claim 12 of the instant application are recited in claims 6 and 7 of the patent. The limitations of claims 45 and 46 of the instant application are recited in claim 11 of the patent. Since the claims of the patent can be said to “anticipate” the broader claims of the instant application, the claims are not patentably distinct.

Allowable Subject Matter

14. Claims 14, 16-44 and 50-54 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. Claims 15 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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16. The following is a statement of reasons for the indication of allowable subject matter:

No prior art of record teach or suggest a sample collection device as recited by Applicant in claim 1 and further including a removable fluid reservoir member in the sample collection housing; a vacuum pump actuating mechanism including an actuating lever pivotally connected to a pump housing; or a vacuum pump means including a flexible diaphragm member and pump actuation means to draw the diaphragm member away from a primary vacuum chamber connected with a sample collection housing.

Response to Arguments

17. Applicant's arguments filed June 24, 2003 have been fully considered but they are not persuasive.

Applicant contends that the rejections made under 35 U.S.C. 102(e) and (f) citing Quay et al. ('521) and the rejections under 35 U.S.C. 102(e) citing Covington et al. ('513) are obviated by the new priority claim for the benefit of the earlier August 27, 1996 filing date of U.S. Application No. 08/709,207. Applicant declined to further address these rejections on the merits. This argument is not persuasive as the priority claim was not granted for the reasons set forth hereinabove. As such, the rejections made under 35 U.S.C. 102(e) and (f) citing Quay et al. ('521) and the rejections under 35 U.S.C. 102(e) citing Covington et al. ('513) are maintained.

Regarding the obviousness-type double patenting rejections citing U.S. Patent No. 6,287,521, Applicant noted "the provisionality of the double patenting rejection and [declined] to address the merits of the rejection until the subject matter is allowed in one of the allegedly conflicting applications." This argument is not persuasive as said double patenting rejections are

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not provisional rejections and the subject matter has been allowed in U.S. Patent No. 6,287,521.

In view of the foregoing, the obviousness-type double patenting rejections citing U.S. Patent No. 6,287,521 are maintained.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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September 30, 2003